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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,860	02/18/2005	Takeshi Koizumi	Q86151	2817

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EXAMINER	
WOOLWINE, SAMUEL C	
ART UNIT	PAPER NUMBER
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,860	KOIZUMI ET AL.	
	Examiner	Art Unit	
	Samuel Woolwine	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-50 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 for the following reason:

37 CFR 1.821(d) requires:

> "Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application."

Applicant is required in response to this Office action to amend claims 10-14, 28-35, and 40-42 to include sequence identifiers (i.e. SEQ ID NOs) for the specific sequences recited in these claims, unless the claims are cancelled. Failure to comply with this requirement in response to this Office action will be deemed non-responsive.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15 and claim 50 in part, drawn to polynucleotides directed to *Vibrio vulnificus gyrB*.

Group II, claim(s) 16-36 and claim 50 in part, drawn to polynucleotides directed to *Vibrio vulnificus rpoD*.

Group III, claim(s) 37-48 and claim 50 in part, drawn to polynucleotides directed to *Vibrio vulnificus recA*.

Group IV, claim 49, drawn to a method for detecting, quantifying or identifying *Vibrio vulnificus*.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: each group named above is drawn to polynucleotides corresponding to distinct genes from the bacterium *Vibrio vulnificus*. Section 803.04 of the MPEP sets forth:

> **>Polynucleotide molecules defined by their nucleic acid sequence (hereinafter "nucleotide sequences") that encode< different proteins are structurally distinct chemical compounds**. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of **35 U.S.C. 121**. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to **35 U.S.C. 121** and **37 CFR 1.141** *et seq.*

Therefore, Groups I-III lack unity of invention *a priori*, since they are drawn to unrelated genes. Furthermore, at least claims 1, 16 and 37 are anticipated by Random Primer 12, sold by New England Biolabs (NEB) (see page 121 of the 1998/99 New England Biolabs Catalog), and therefore Groups I-III cannot share a special technical feature with Group IV. The following calculations rely on facts provided on page 284 of the catalog, specifically the mass of 1.0 A_{260} unit of single-stranded DNA and the molecular weight of single-stranded DNA per nucleotide (i.e. half the weight of a double-stranded DNA per basepair).

Random 12-mer:

Molecular weight of 12-mer:
12×325 daltons/nucleotide = 3,900 daltons = 3,900 g/mol

Number of possible 12-mers:
$4^{12} = 1.7 \times 10^{7}$ molecules; there are four possible bases, so 4^{12} possible combinations of 12 bases

How many molecules of 12-mer in a vial sold by NEB:
1 A_{260} unit = 33 μg = 3.3×10^{-5} g
3.3×10^{-5} g ÷ 3,900 g/mol = 8.5×10^{-9} mol
$(8.5 \times 10^{-9}$ mol) × $(6.02 \times 10^{23}$ molecules/mol) = 5.1×10^{15} molecules; 6.02×10^{23} is the number of molecules per mole according to Avogadro's number.

How many vials needed to sum to 1 of each possible 12-mer:
$(1.7 \times 10^{7}$ types of molecule) ÷ $(5.1 \times 10^{15}$ molecules per vial) = 3.3×10^{-9} vial

Put another way, one vial of random 12-mer sold by NEB contains enough material to provide 3×10^8 molecules of each possible 12-mer.

Therefore, every possible 12-mer would have been present in a vial of Random Primer 12 sold by NEB. This includes ever 12-mer found within the sequences of SEQ ID NOS 1, 2 and 3 (thus anticipating claims 1, 16 and 37).

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The species encompassed within each group are too numerous to list. The species correspond to all the various polynucleotides containing all the various combinations of one or more of the positions recited in claims 1 (for Group I), 16 (for Group II) and 37 (for Group III). Additional species correspond to the particular sequences recited in claims 10-14 (Group I), claims 28-35 (Group II), and claims 44-47 (Group III).

Applicant is required, in reply to this action, to elect a single species (i.e. a single combination of positions (recited in the independent claims 1, 16, or 37) or a single particular sequence (as recited in claims 10-14, 28-35, or 44-47) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 4, 6 and 7 correspond to particular species of combinations of positions for Group I.
Claims 10-14 correspond to particular species of sequences for Group I.
Claims 2, 3, 5, 8, 9, 15 and 50 encompass multiple species of combinations of positions for Group I.

Claims 19, 20, 21, 22, 23, 24 and 25 correspond to particular species of combinations of positions for Group II.
Claims 28-35 correspond to particular species of sequences for Group II.
Claims 17, 18, 26, 27, 36 and 50 encompass multiple species of combinations of positions for Group II.

Claims 40 and 41 correspond to particular species of combinations of positions for Group III.
Claims 44-47 correspond to particular species of sequences for Group III.
Claims 38, 39, 42, 43, 48 and 50 encompass multiple species of combinations of positions for Group III.

The following claim(s) are generic: 1, 49 and 50 (for Group I), 16, 49 and 50 (for Group II), and 37, 49 and 50 (for Group III). It is noted that claims 2 and 15, 17 and 36, and 38 and 48 represent particular species of the polynucleotides claimed in claims 1, 16 and 37, respectively, which are 15 or more nucleotides in length.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: as discussed above, at least one species for each group is anticipated by Random Primer 12, sold by NEB.

Due to the complex nature of the election being required, a written restriction requirement is being sent in lieu of a telephonic request. See MPEP § 812.01. However, Applicant is encouraged to contact the examiner at the number listed below for assistance or questions related to this election.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is

subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Woolwine whose telephone number is (571) 272-1144. The examiner can normally be reached on Mon-Fri 10:30 am-7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

scw

YOUNG J. KIM
PRIMARY EXAMINER
3-8-07